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Supreme Court of the United States

OCTOBER TERM, 1949.

No. 463

FRED URBUTEIT, CLAIMANT OF 16 ARTICLES OF DEVICE, MORE OR LESS, LABELED "SINUOTHERMIC," PETITIONER,

VS.

THE UNITED STATES OF AMERICA.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT.

H. O. PEMBERTON,
Tallahassee, Florida,
Attorney for Petitioner.

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Supreme Court of the United States

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VS.

THE UNITED STATES OF AMERICA.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT.

Fred Urbuteit prays:

1. That a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Fifth Circuit granting the motion of the United States to affirm the decree of the United States District Court for the Northern District of Florida whereby certain articles of device were condemned as misbranded under Section 304 of the Federal Food, Drug and Cosmetic Act, and to review

the judgment of said Court of Appeals denying a petition for a rehearing thereon.

2. That this Court clarify its own opinion of May 2, 1949 (No. 640, October Term, 1948), reported in 69 S. Ct. 840, by removing therefrom an erroneous statement which it derived from false statements in the pleadings and briefs of the United States, and by making it clear to the Court of Appeals that it was not the intent of this Court to compel the granting of the motion of the United States to affirm the judgment of the District Court, but simply to require the consideration of and the judicial determination of the question presented by that motion.

3. That the judgment of the Court of Appeals be reversed and this cause remanded with directions to said Court to hear and consider the motion to affirm on its merits only.

JURISDICTION.

The judgment of the Court of Appeals was entered August 2, 1949, and a petition for rehearing denied September 13, 1949. The jurisdiction of this Court is invoked under 28 U. S. C. 1254 (1).

QUESTIONS PRESENTED.

1. Whether the Court of Appeals complied with the mandate of this Court in failing to hear and consider on its own merits the motion of the United States to affirm the decree of condemnation, and in granting said motion as a ministerial act *compelled* by the opinion of this Court.

2. Whether the Court of Appeals erred in granting the motion of the United States to affirm the decree of con-

demnation when said motion was based on the theory that testimony offered but erroneously excluded by the District Court, and for which exclusion the District Court was reversed, would have related only to the *therapeutic* value of the devices; when in truth and in fact the excluded testimony was offered for the purpose of proving and would have related to both the *diagnostic* and the *therapeutic* value of the devices.

REASONS FOR ALLOWANCE OF THE WRIT.

In its two earlier appearances before this Court on petitions for certiorari filed by the United States the construction of the Federal Food, Drug and Cosmetic Act as regards shipments of devices and literature in interstate commerce was involved principally. The present petition has no relation to that subject matter. Five members of this Court as at that time constituted construed the Act and although the writer of this petition sincerely believes the reasoning and conclusion of the minority four to be right, this present petition is in no sense an effort to have the question reviewed.

The question with which we are concerned in this petition has arisen because of a false representation made repeatedly in the pleadings and briefs filed in this case by the United States. Hitler developed this vicious art to near perfection and mentions its psychological essentials in his "Mein Kampf."

At the trial in the District Court the Claimant, who is the petitioner here, made a proffer of testimony that was excluded by the District Judge. A part of that proffer is as follows:

> "* * * Claimant further offers to testify as to his diagnosis with the use of the Sinuothermic machine,

and otherwise, with reference to the persons whose testimony as to their treatment would be offered, and to testify as to his treatment of such persons and the results obtained from such treatments" (R. 162, No. 13, October Term, 1948).

It is apparent from the above quoted proffer that the testimony offered but excluded would have dealt with comparative diagnosis of specific cases with the device in question and with other means of diagnosis, and the accuracy of the diagnosis in each instance (diagnosis with the device and diagnosis by other methods) as later determined by treatment and the results obtained therefrom. This testimony, both as to the therapeutic and the diagnostic values of the device, was highly important and the Court of Appeals reversed the District Court for excluding it and the testimony of some thirty patients or former patients of Dr. Urbuteit, the claimant (R. 182-183, No. 13, October Term, 1948).

When the case was brought to this Court on petition for certiorari by the United States the principal question argued had to do with the interpretation of the law but as the case stood reversed on the exclusion of testimony also the petitioner tried to dodge the effect of this reversal. The error was so clear that the reversal based on the exclusion of testimony was not even assigned as error on the part of the Court of Appeals in the petition to this Court. Instead, a twisting and distortion of the record was resorted to, and we find the following language in the Petition for Certiorari (No. 577, October Term, 1947). page 12, under Specification of Errors to Be Urged:

"3. In failing to affirm the judgment of the district court because of false and misleading claims of diagnostic capabilities despite alleged errors in ex-

clusion of evidence offered to show the claimed therapeutic values of the machines.[3]"

and then in the footnote the following language:

"[3]Error is not assigned as to the rulings below with respect to the exclusion of evidence by the trial court. For reasons hereinafter set forth (pp. 18-21), petitioner submits that even if the court below did not err in holding the excluded evidence admissible petitioner is entitled to a judgment of condemnation because of admittedly false representations on an issue to which the excluded evidence did not pertain."

This type of misrepresentation of the record continued from that point on. Without burdening the Court with quotations from each of the documents filed by the Government attorneys we will skip to the Motion to Affirm filed in the Court of Appeals where we find the following language:

"The evidence which this Court held improperly excluded was offered to prove that claims of therapeutic or curative value made for the machines were true (R. 158-163). It had no relationship to the truth or falsity of claims of diagnostic ability" (R. 5, No. 640, October Term, 1948) and also (R. 6, this petition).

This Court apparently did not intend to pass on the merits of the claim of the United States that it was entitled to affirmance of the decree of condemnation because the excluded evidence would not have pertained to the diagnostic value of the device, and for that reason this Court apparently did not make a careful study of the record relating to the use of the device. As a result, this Court was misled and we find in its first opinion this final paragraph:

"The Court of Appeals held that certain evidence tendered by Urbuteit as to the therapeutic or curative

> value of the machines had been erroneously excluded at the trial, a ruling that we are not inclined to disturb. Petitioner claims, however, that the error was not prejudicial. The argument is that since the evidence of the false and misleading character of the advertising as respects the diagnostic capabilities of the machines was overwhelming, that false representation was adequate to sustain the condemnation, though it be assumed that the therapeutic phase of the case was not established. We do not reach that question. Since the case must be remanded to the Court of Appeals, that question and any others that have survived will be open for consideration by it." *U. S. v. Urbuteit*, 335 U. S. 355.

The opinion from which the above quotation is taken dealt principally with the matter of shipment in interstate commerce. When the case was remanded to it the Court of Appeals again reversed the District Court, ordering further investigation into the relationship between advertising and machine shipments, but made no mention of the claim set forth in the above quotation other than to dispose of it in the following sentence:

> "The Supreme Court did not disturb our former ruling that the district court should have heard all the evidence offered on the question of the falsity of the advertising. We adhere to that ruling."

Is there anything in that statement about evidence as to therapeutic value? It is apparent that the Court of Appeals, having studied all the evidence carefully, looked upon the excluded evidence as vital and pertaining to both diagnostic and therapeutic value. Then the case came back to this Court on a second petition for certiorari by the United States and the claim that the Court of Appeals failed to follow the mandate of this Court when it ordered a retrial of the interstate commerce question and in

"failing to consider whether the Government is entitled to a decree of condemnation because of the false character of the advertising matter as respects the diagnostic capabilities of the devices" (No. 640, October Term, 1948, Petition, page 3).

We come now to this Court's last opinion and that part of it which answers the assignment of error just quoted. The same erroneous statement is picked up and used again:

> "On remand the Court of Appeals adhered to its former ruling that the District Court erroneously excluded evidence as to the therapeutic or curative value of the machines. When the case was here before we did not disturb that ruling. But we did leave to the Court of Appeals for consideration a further question —whether the evidence as respects the falsity of the diagnostic capabilities of the machine was adequate to sustain the condemnation even though error in exclusion of the other evidence were conceded. The United States is entitled to a hearing on that question" (No. 640, October Term, 1948). *U. S.* v. *Urbuteit*, 69 S. Ct. 840.

When this opinion reached the Court of Appeals, that Court, with the exception of Judge Sibley, threw in the sponge, without so much as one word of comment:

> "*Per Curiam*: The motion to affirm is granted."

U. S. v. *Urbuteit*, ... U. S. ..... (May 2, 1949) (R. 10). and then Judge Sibley begins his dissenting opinion:

> "My brethren feel compelled by the opinions of the Supreme Court in this case to grant the Government's motion to affirm the decree of the District Court forfeiting the sixteen electric machines seized as misbranded. * * *"

Even Judge Sibley did not realize that this Court did not intend to interpret the evidence but that this Court

had simply erroneously picked up and used the false statement that the excluded evidence did not pertain to the diagnostic value of the device, so he goes on to point out that even admitting false labeling as regards diagnostic value, still a number of machines would not be subject to condemnation without further evidence because they had not been shown to have been represented as useful in diagnosis.

Here is clearly a case of misunderstanding of what was intended. The writer of this petition, having argued the case before both the Court of Appeals and the Supreme Court and having tried it in the District Court, believes that he understands what was in the minds of the members of both the Supreme Court and the Court of Appeals. He believes that the Supreme Court never intended to state as a fact it had adjudicated that the excluded evidence would not have pertained to the diagnostic value of the devices, but that the Supreme Court simply meant to say that here is a question the Government has raised—you pass on it. He also believes that the Court of Appeals interpreted the opinions of the Supreme Court to mean that the excluded evidence would have pertained only to therapeutic and not diagnostic value and that the Court of Appeals must consider only the evidence admitted and not the exclusion of other evidence in passing on the motion of the United States to affirm the decree of condemnation. There certainly was not a "meeting of the minds" of the two Courts on what the opinions of the Supreme Court decided and required.

It is respectfully submitted that unless this Court clarifies its opinions by correctly stating what the record shows to be the nature of the evidence offered and excluded, and by making it clear to the Court of Appeals that this Court had no intention of compelling any action

with relation thereto other than consideration on its merits of the motion to affirm, a gross and irreparable injustice will have been done to the petitioner, Dr. Fred Urbuteit —and a feeling of resentment or something akin to it will linger in the minds of the members of the Court of Appeals. To that end this petition should be granted.

H. O. PEMBERTON,
Tallahassee, Florida,
Attorney for Petitioner.

November, 1949.

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In the Supreme Court of the United States

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No. 463

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v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The majority (R. 10) and dissenting (R. 10-13) opinions of the Court of Appeals are reported at 176 F. 2d 438. The two earlier opinions of that court are reported, respectively, at 164 F. 2d 245 and 172 F. 2d 386. The opinions of this Court, reversing the earlier judgments of the Court of Appeals, are reported, respectively, at 335 U. S. 355 and 336 U. S. 804.

JURISDICTION

The judgment of the Court of Appeals was entered August 2, 1949 (R. 14). The judgment affirmed the decree of condemnation of the trial court entered January 27, 1947 (Record, No. 13, Oct. Term 1948, 168-169). A motion for rehearing was denied by the Court of Appeals September 13, 1949 (R. 17). The petition for a writ of certiorari was filed November 23, 1949. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTION PRESENTED

Whether the Court of Appeals erred in granting the Government's motion to affirm the decree of condemnation based upon a showing that there was undisputed evidence before the trial court with respect to the false claims of diagnostic capabilities made for the Sinuothermic machines.

STATUTE INVOLVED

The Federal Food, Drug, and Cosmetic Act of June 25, 1938, c, 675, 52 Stat. 1040 (21 U.S.C. 301 *et seq.*), provides in pertinent part:

SEC. 201. For the purposes of this Act—

* * *

(h) The term "device" * * * means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; * * *

* * *

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

SEC. 304. (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found * * *

SEC. 502. A drug or device shall be deemed to be misbranded—(a) If its labeling is false or misleading in any particular.

STATEMENT

This case, a libel for condemnation action instituted under the Federal Food, Drug, and Cosmetic Act, was tried in the Northern District of Florida. Findings of fact, conclusions of law (No. 13, Oct. Term 1948, 163-167) and a decree of condemnation (No. 13, R. 168-169) were entered January 27, 1947. On appeal to the Court of Appeals for the Fifth Circuit, a judgment was entered reversing the decree of condemnation and remanding the cause for proceedings not inconsistent with the court's opinion (No. 13, R. 179-183, and 164 F. 2d 245). The reasons for reversal were (1) that the trial court had erred in holding that the leaflet "The Road to Health" constituted labeling within the

meaning of Section 201(m) of the Federal Food, Drug, and Cosmetic Act; (2) that the trial court had erred in refusing to hear the testimony of 30 patients as to "whether their external symptoms abated and their pains ceased" after treatment with the machines; and (3) that the trial judge had erroneously refused to accept the expert opinion testimony of the claimant, Dr. Urbuteit, as to diagnoses of the patients' diseases and ailments (No. 13, R. 179-183, 164 F. 2d 245).

Thereafter, on petition by the Government restricted to the issue whether the leaflet constituted labeling, this Court granted certiorari (333 U. S. 872) and heard the case together with the companion case of *Kordel* v. *United States,* 335 U. S. 345. The Government urged that the relationship of the leaflets to the devices was such that they constituted labeling within the meaning of Section 201(m) of the Act. The Government also contended that even if it were assumed that the District Court had erred in excluding the proffered evidence relating to the curative value of the machines, the Government was entitled to a decree of condemnation (if it prevailed on the "accompaniment" issue), since it appeared from the undisputed testimony and from Dr. Urbuteit's own admissions that the machines did not possess the diagnostic capabilities claimed for them. This Court held that the leaflets had accompanied the devices so as to constitute labeling under the Act.

In reversing the judgment of the Court of Appeals, this Court did not disturb the ruling below that the trial court had erred in excluding petitioner's proffered testimony, and this Court said that since the cause must be remanded to the Court of Appeals, the question whether the Government was entitled to a decree of condemnation because of the falsity of the claims made in the leaflets in respect of the diagnostic capabilities of the devices would be open for consideration by the Court of Appeals, together with any other questions that had survived.

On the remand, the Government filed a motion in the Court of Appeals to affirm the decree of condemnation. The Government urged, as it had urged in this Court (see our brief in No. 13, pp. 37-41), that error in excluding the testimony relating to curative properties of the device did not affect the Government's right to a decree of condemnation bottomed on the undisputed evidence of misbranding in respect to the falsification of the device's value in diagnosing diseases (No. 640, Oct. Term 1948, R. 1-6). The Court of Appeals did not consider this contention. Instead, it construed the opinion of this Court as holding merely that "certain advertising matter shipped separately from any of the machines and held by us for that reason not to have 'accompanied' any of them *might* nevertheless constitute 'labeling', *if* the movements of advertising and machines in interstate commerce were a single interrelated activity and not separate or isolated ones." (Italics supplied.) The court

adhered to its earlier ruling that the trial court had erred in excluding petitioner's proffered testimony referred to above, and concluded that the judgment should be reversed and the cause remanded to the trial court "for further proceedings in conformity with the opinion of the Supreme Court and with this opinion." (No. 640, R. 6-7, 172 F. 2d 386.)

This Court again granted a writ of certiorari and reversed the judgment of the Court of Appeals (336 U. S. 804 and R. 8-10). This Court declared in part:

> * * * we did leave to the Court of Appeals for consideration a further question—whether the evidence as respects the falsity of the representations regarding the diagnostic capabilities of the machines was adequate to sustain the condemnation even though error in exclusion of the other evidence were conceded. The United States is entitled to a hearing on that question.

On June 1, 1949, the Government renewed its motion to affirm in the Court of Appeals (R. 1-7). The motion was granted on August 2, 1949, Judge Sibley dissenting (R. 10-13). A motion for rehearing was denied September 13, 1949 (R. 17).

ARGUMENT

The Court of Appeals did not err in granting the motion to affirm. The petition for a writ of certiorari now before this Court asserts that the Court of Appeals misunderstood this Court's opinion (Pet. 2, 7-8). It is argued, upon the basis of an

inference drawn from Judge Sibley's dissenting opinion, that the Court of Appeals did not feel free to consider the question that was left to it. Petitioner contends that the Court of Appeals granted the motion to affirm without giving it judicial consideration. The assumptions upon which these arguments are made find no support in the record.

The Government's motion to affirm (R. 1-7) demonstrated the following:

The leaflet "The Road to Health"[1] makes the unqualified claim that the Sinuothermic machine will diagnose disease without guesswork and will make it unnecessary to have "someone guess at what your ailment is." It represents that the machine "locates the cause" of any ailment and "registers exactly". Pertinent portions of the leaflet were quoted in the motion to affirm (R. 3-4). The labeling does not differentiate between the large and the small machines in this respect.

The trial court found, upon consideration of the leaflet, that it represented that the machines (without differentiation) are effective in the diagnosis of a large number of diseases. (No. 13, Oct. Term 1948, Finding 4, R. 165).

The evidence at the trial revealed that each of the Sinuothermic machines consists of a number of

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[1] The leaflet is not reproduced in the record in No. 13, October Term 1948, but copies are on file with the clerk. See the excerpts from the leaflet quoted in the motion to affirm (R. 3-4).

electrical units mounted in a wooden cabinet. The machine draws electricity from an ordinary household wall socket, controls the full line voltage (electrical pressure) by turning in variable amounts from zero to 115-120 volts, steps this voltage down to a maximum volume of 60 volts, and delivers current to the patient so that it will flow through the human body between two pad electrodes that are applied to the bare skin (No. 13, Oct. Term 1948, R. 39-44, 50-52, 164). The small machines differ from the large ones only in the omission of four indicating meters (No. 13, R. 43, 164).[2]

The undisputed evidence was that the machines—including the ones which had meters—were without value in the diagnosis of disease (No. 13, R. 72, 76,

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[2] In proving the case in the trial court, the Government, on its own initiative, drew a distinction between the large machines and the small ones. This was done by demonstrating that, while the machines differed in external appearance, they were the same in their principles of operation (No. 13, R. 43). The Government showed, without dispute, that the indicating meters, which caused the major difference in external appearance, served no purpose in the practical application of the machine, either in diagnosing or in treating.

The 3 volt meters registered only electrical pressure (voltage) at different points in the machine's electrical circuit. The first one registered line voltage, i.e., that voltage delivered to the wall socket from the city's source of power (No. 13, R. 39-40, 51). The second volt meter registered the amount of voltage that passed through the potentiometer (a control switch.) This was variable between 0-120 volts (No. 13, R. 40, 51). The third volt meter registered voltage after the electricity had passed through the step-down transformer (No. 13, R. 40, 51). The milliampere meter registered the flow of current through the human body when contact was made with the pad electrodes (No. 13, R. 40, 51). The number of milliamperes of current (electrical flow) was not affected by pathological changes in the body (No. 13, R. 43, 52, 61).

79-80, 83-85, 88-89, 91, 93, 96-97, 99-100, 104-105, 109-112). Urbuteit himself admitted that the devices, used alone, are incapable of diagnosing any disease (No. 13, R. 126-127, 128-130). The Court of Appeals, in its first opinion, observed that Urbuteit's testimony "only claimed the machine to be an aid in diagnosing", and stated that his testimony as a whole was that the machine did not indicate any particular disease but only located the spot where the abnormal tissue was (No. 13, R. 182, 164 F. 2d 245, 247).

With respect to diagnostic claims, the trial court found that the leaflets represented that the devices would register the exact nature of any disease and would diagnose disease, but found that it is not possible to correlate body resistance to electrical current with pathological changes in the body (Finding 5), and that the underlying principles upon which the machines were claimed to operate were impossible of practical application with these instruments (No. 13, Findings 4-5, 7, R. 165-166).

The falsity of the diagnostic claims was established by the Government and admitted by Urbuteit. Under the Federal Food, Drug, and Cosmetic Act it is not necessary that the Government prove that the labeling representations are false and misleading in all respects. The decree of condemnation was properly affirmed upon a showing that any one of the various claims made in the labeling was either false or misleading in any particular. Section 502(a); *Goodwin* v. *United States,*

2 F. 2d 200, 201 (C.A. 6); *United States* v. *Six Dozen Bottles* * * * *Kuriko,* 158 F. 2d 667, 669-670 (C.A. 7); and *United States* v. *One Device* * * * *Colonic Irrigator,* 160 F. 2d 194, 200 (C.A. 10).

It was made clear in the motion to affirm that the evidence which the Court of Appeals held to have been improperly excluded had been offered to prove the truth of claims of therapeutic or curative value (No. 13, R. 158-163), and had no bearing upon the truth or falsity of claims of diagnostic ability.

In its first opinion the Court of Appeals held that the evidence as to diagnoses had been improperly excluded because Urbuteit was entitled to express expert opinions based upon his training and experience as a licensed naturopath, since his testimony as a whole showed that he used all known methods of diagnosis and used the machines only as an aid in diagnosing (164 F. 2d 245, 247). But testimony of such diagnoses made by means other than the machine would not tend to show in any way that the machine was capable of making an accurate diagnosis of any disease. The petition for certiorari states that the excluded evidence would have dealt with comparative diagnoses of specific cases, comparing the diagnostic capabilities of the device in question with other diagnostic procedures. (Pet. 4.) Neither the trial court nor the Court of Appeals so understood it. And that assertion is clearly inconsistent with the testimony offered by

Urbuteit at the trial. Certainly the testimony of laymen that their external symptoms abated and their pains ceased upon treatment with the machines would establish nothing respecting diagnostic capabilities.

It is clear from the record that the evidence which the Court of Appeals held to have been improperly excluded had no relationship to the claims of diagnostic ability. This point was argued before the Court of Appeals both upon the motion to affirm (R. 1-7) and the petition for rehearing (R. 14-17), and there is no reason to believe that it was not fully understood. In fact, the petition for rehearing emphasizes the point that Dr. Urbuteit was not prepared to prove that the machines had any diagnostic capacity. Instead, petitioner asserts that exact diagnosis is unimportant in his method of treatment because, he claims, patients get well under the machine treatment without diagnosis (R. 15-16).

CONCLUSION

The petition for certiorari makes no showing that the issue decided below is of that degree of importance that would warrant this Court in granting the petition for a writ of certiorari. No conflict of decisions is presented. The dissenting opinion is based upon Judge Sibley's disagreement with the decisions of this Court on the "accompaniment" issue.

For the foregoing reasons, we respectfully submit that the petition for a writ of certiorari should be denied.

PHILIP B. PERLMAN,
Solicitor General.
ALEXANDER M. CAMPBELL,
Assistant Attorney General.
ROBERT S. ERDAHL,
VINCENT A. KLEINFELD,
Attorneys.

WILLIAM W. GOODRICH,
Attorney,
Federal Security Agency.

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